

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 23, 2008 has been entered.

## **EXAMINER'S AMENDMENT**

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Attorney Daniel Spillman on June 19, 2009.

The application has been amended as follows:

**Claim 2** has been cancelled.

**Claim 3** has been cancelled.

**Claim 11** has been cancelled.

**Claims 29-42** have been cancelled.

**Claim 43** (Currently Amended) A method of manufacturing an implantable valve prosthesis for a tubular bodily passage, comprising the steps of:

providing a flexible biomaterial and a support frame including a plurality of bends and interconnected sides to define a closed circumference with an aperture therethrough, the support frame includes a first configuration for intravascular delivery into said bodily passage and a second configuration for implantation therein, the plurality of bends in the first configuration comprising at least a first pair of opposite bends and a second pair of opposite bends;

forming a slit in the flexible biomaterial;

placing the flexible biomaterial against the support frame such that an overhang portion thereof extends beyond the closed circumference;

orienting said slit between one of the first and second pair of opposite bends;

folding the overhang portion of the flexible biomaterial over the sides, generally enclosing the sides within the folded overhang portion;

welding a portion of the folded overhang portion to itself by a series of heat welds along the sides and bends to secure the folded overhang portion of the flexible biomaterial to the sides enclosed therein;

~~(forming a slit between one of the first and second pair of opposite bends;)~~ and

folding the support frame to the second configuration about a diagonal axis across the aperture of the support frame by bringing the first pair of opposite bends in closer proximity to

form a first end of said implantable prosthesis and the second pair of opposite bends in closer proximity to form a second end of said implantable valve prosthesis.

3. The following is an examiner's statement of reasons for allowance: the Prior Art does not disclose or suggest a method of manufacturing an implantable valve prosthesis for a tubular bodily passage, particularly the method steps of:

providing a flexible biomaterial and a support frame including a plurality of bends and interconnected sides to define a closed circumference with an aperture therethrough, the support frame includes a first configuration for intravascular delivery into said bodily passage and a second configuration for implantation therein, the plurality of bends in the first configuration comprising at least a first pair of opposite bends and a second pair of opposite bends;

forming a slit in the flexible biomaterial;

placing the flexible biomaterial against the support frame such that an overhang portion thereof extends beyond the closed circumference;

orienting said slit between one of the first and second pair of opposite bends;

folding the overhang portion of the flexible biomaterial over the sides, generally enclosing the sides within the folded overhang portion;

welding a portion of the folded overhang portion to itself by a series of heat welds along the sides and bends to secure the folded overhang portion of the flexible biomaterial to the sides enclosed therein; and

folding the support frame to the second configuration about a diagonal axis across the aperture of the support frame by bringing the first pair of opposite bends in closer proximity to

form a first end of said implantable prosthesis and the second pair of opposite bends in closer proximity to form a second end of said implantable valve prosthesis.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:00 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on **(571)272-4749**. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Javier G. Blanco/

Examiner, Art Unit 3774

/David H Willse/

Primary Examiner, Art Unit 3738